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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,331	10/17/2003	David T. Bach		2309

7590 02/27/2006

Clifford Kraft
320 Robin Hill Dr.
Naperville, IL 60540

EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,331	BACH ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17-19,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15, 17-19, 21-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-15, 17-19 and 21-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-15, 17-19 and 21-22 have been amended to recite a "stepping precision pump". However, the specification, as originally filed, only describes a "precision fluid pump" or a "precision pump". See pages 6-7 and 11 of the instant specification. Nowhere in the specification, as originally filed, is a stepping precision pump described or explained, and therefore, this new limitation constitutes new matter.

3. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 3 of claim 21, the phrase "said selected cell" lacks antecedent basis, and should be changed to –said desired cell—in order to use the terminology used in claim 1.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-15 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diessel et al in view of Wada et al.

Diessel et al teach of a method and apparatus for sorting biological cells. The method comprises flowing a cell stream 2 through a feed inlet 1, which leads to individual sorting modules 4. After sorting, the streams of positive and negative channels from each sorting module unite to form a collecting channel 5 for positive cells and a collecting channel 6 for negative cells. Each sorting module comprises a main channel 3 with an optical detection system located there along. The optical detection system comprises both a light scatter sensor 9 and a fluorescence sensor 10. Downstream of the optical detection system is located a switch unit 11

with a sorting actuator 12. The cells to be sorted are classified with the scattered light sensor and the fluorescence light sensor according to their size and other parameters. Light is introduced into the channel 3 via light guides from an illumination device 13 arranged outside the channel. Detectors 9 and 10 are connected via lines 14 to an evaluation and control electronics 15, which is connected via line 16 to the sorting actuator 12. Diessel et al teach that the main channel 3 with the switch unit 11, the optical sensors 9 and 10, the sorting actuator 12 and the evaluation and control electronics 15 are integrated into a monolithic silicon chip. The sorting actuator 12 brings about a diversion of cell flow to either a cell outlet channel 19 or a waste channel 20 depending upon the signal from the optical sensors sent to the control electronics 15. Diessel et al teach that many different actuator sorting principles are suitable for use in the device. One of the actuator principles that can be used is a magnetostrictive actuator in the form of flexible tongues in the channel 3 at the location of the two channels 19, 20. The magnetostrictive tongues can bend under the influence of an external magnetic field due to magnetostrictive forces. This causes a narrowing of the cross-section of the channel 20 that causes the cell stream to flow out of the channel 19. See Figures 1-2, 3A, 3B, lines 44-67 in column 3, lines 1-57 in column 4 and lines 2-5 in column 5 of Diessel et al. Diessel et al fail to teach of a precision pump and vacuum for causing the cell stream to flow through the channels 3, 19 or 20, and fail to teach that the optical detection system can comprise a photomultiplier or a diode array.

Wada et al teach of a microfluidic device for sorting cells that comprises a channel network in fluid communication with multiple wells and reservoirs. The channel network includes a main analysis channel and one or more side channels connecting the reservoirs to the main channel. Cells are flowed through the side channels and into the main channel by a flow

controller in the form of one or more constant or variable pressure or vacuum sources. Wada et al teach that the flow controller can be a positive displacement pump, a peristaltic pump or another type of common pump. In addition, the flow controller can be a vacuum source for drawing fluid through the channels of the device. An optical detection system located along the length of the main channel serves to detect and analyze cells flowing there through. The optical detection system can measure light scattering or fluorescence by means of a photodiode or a photomultiplier. In addition, multiple optical detectors can be used for detecting different signals during operation of the system. See paragraph nos. 0034-0035, 0038, 0040, 0041, and 0055-0057 of Wada et al.

Based upon the combination of Diessel et al and Wada et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use a precision pump or a vacuum to move the cell-containing fluid through the channels in the device taught by Diessel et al since Wada et al teach that pumps or a vacuum are common flow controllers used to flow a cell-containing stream to be sorted through a channel network, such as that included in the device of Diessel et al. It also would have been obvious to one of ordinary skill in the art to use one or more diodes or photomultipliers as the optical detection system in the device taught by Diessel et al since Wada et al teach that these are common optical sources and detectors for evaluating a cell to be sorted flowing through a channel network.

8. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diessel et al in view of Wada et al as applied to claims 1-15 and 21-22 above, and further in view of Clark. For a teaching of Diessel et al and Wada et al, see previous paragraphs in this Office action.

Diessel et al fail to teach that the magnetostrictive sorting actuator in the device for sorting cells is a magnetostrictive rod that can change length in response to a magnetic field.

Clark teaches of a magnetostrictive transducer used to control fluid flow through a channel. The transducer comprises a magnetostrictive rod 12 disposed within a fluid flow channel 10. The rod is initially in close fitment with a discharge port 14 to restrain the flow of fluids through the port 14. When a magnetic field is created around the assembly, the housing expands and the rod contracts, causing the rod to separate from close, seated fitment with the discharge port 14, thereby allowing flow through the port. See Figures 1a-1c, lines 37-68 in column 3 and lines 1-29 in column 4 of Clark.

Based upon the combination of Diessel et al, Wada et al and Clark, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use a magnetostrictive rod, such as the one taught by Clark, as the magnetostrictive sorting actuator in the cell sorting device taught by Diessel et al since Clark teaches that a magnetostrictive rod located in a fluid flow channel can either allow or stop the flow of fluid in the channel depending upon its exposure to an external magnetic field, which is equivalent to the magnetostrictive narrowing or widening of the fluid flow channel taught by Diessel et al.

9. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diessel et al in view of Wada et al as applied to claims 1-15 and 21-22 above, and further in view of Kamentsky et al. For a teaching of Diessel et al and Wada et al, see previous paragraphs in this Office action. Diessel et al fail to teach that the optical detection system for measuring cell parameters flowing through the device contains optical fibers for conveying light from a source into the main channel.

Kamentsky et al teach of a particle sorter, which comprises a stream of particles 29 flowing through a central channel. An optical detection system is located along the channel to measure cell parameters that consists of a light source 30 on one side of the channel and photoresponsive pick-up elements 42 and 44 located on the opposite side of the channel. Kamentsky et al teach that fiber optics may be employed to carry light illumination from a lamp to the channel and from the channel to a photoelectric pick-up element. The cells are then sorted into one of two outlet channels 62 or 64. See Figure 1, lines 56-67 in column 2, lines 1-25 in column 3, lines 45-50 in column 5 and lines 43-54 in column 8 of Kamentsky et al.

Based upon a combination of Diessel et al and Kamentsky et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to include optical fibers in the optical detection system of the cell sorter taught by Diessel et al since Diessel et al disclose that light guides are used in the optical detection system, and Kamentsky et al teach that optical fibers are a type of light guide to guide light from a source into a fluid flow channel for detecting cells in the fluid.

10. Applicant's arguments filed December 27, 2005 have been fully considered but they are not persuasive.

The previous rejections of the claims under 35 USC 112, second paragraph made in the last Office action mailed on September 22, 2005 have been withdrawn in view of Applicants' amendments to the claims. However, new claim 21 is now rejected under this statute as set forth above.

Applicants argue the previous rejections of the claims under 35 USC 102 and 35 USC 103 using the references to Diessel et al, Wada et al, Clark and Kamentsky et al by stating that

none of the references teach or suggest controlling the motion of fluid in a cell sorter using a stepping precision pump by causing the pump to stop its motion when the desired cell is detected in the correct position to enter an exit port, causing a sorting gate to select a cell collection port rather than a waste port, pumping exactly the amount of fluid to cause the selected, desired cell to enter the cell collection port, and changing the position of the sorting gate back to the waste port.

In response to this argument, it is noted that the primary reference to Diessel et al teaches of a cell sorter device having a sorting gate therein that is controllably caused to choose either a waste port or a collection port in response to a signal from an optical cell detector located upstream of the sorting gate. If a desired cell is detected by the optical detector, then the sorting gate is caused to close the waste port while opening the collection port for a short time period so that the desired cell can exit the cell sorter through the collection port. Once the desired cell exits the cell sorter through the collection port, the sorting gate is once again caused to return back to the original configuration of an open waste port and a closed collection port. This process is repeated the next time a desired cell is detecting in the sorting module by the optical detection system. Therefore, the primary reference to Diessel et al teaches of each of the limitations in instant claims 1-15 and 21-22 with the exception of a stepping precision pump for causing the flow of fluid containing cells through the sorting module, and the intermittent stopping of the pump when a desired cell is detected with the optical detection system, as well as the controlled movement of the pump to cause only a desired cell to enter the cell collection port. However, the secondary reference to Wada et al teaches of precision fluid pumps to control the movement of fluid containing cells through a capillary by starting and stopping the motion of the

fluid through the capillary, a waste port and a collection port. Wada et al teach that a pressure controller such as a syringe pump, a peristaltic pump or a diaphragm pump can be used to control the movement of a cell-containing fluid through a cell sorting capillary. See paragraph no. 0040 in Wada et al. Each of a syringe pump, a peristaltic pump and a diaphragm pump are well-known precision fluid pumps that can allow for either continuous flow or pulsed flow by allowing the stopping and starting of fluid flow in a channel. Wada et al teach that the flow of fluid in the capillary can be stopped. See paragraph no. 0047 in Wada et al. In addition, Wada et al teach of controlling fluid flow containing cells therein between a waste port and a collection port by the use of the pressure controller (i.e. pump). When a desired cell is detected at the detection window in the cell sorter taught by Wada et al, the pressure controller (pump) adjusts the pressure and flow of fluid in the capillary such that the flow of the desired cell is directed towards the collection port. Once the desired cell passes through the collection port, the flow is switched back to the waste port. See paragraph no. 0049 in Wada et al. The precision pumps taught by Wada et al allow for the flow of cell-containing fluid in the capillary to be stopped long enough to controllably direct the fluid containing either a desired cell or not containing a desired cell to either a collection port or a waste port. Therefore, the secondary reference to Wada et al teaches of the limitation in the instant claims concerning a precision pump stopping its motion when a desired cell is detected in the optical detection region thus allowing the proper collection port or waste port to be selected, and then controllably moving the pump to allow only the fluid containing a desired cell to exit the collection port before the waste port is once again selected. Based upon the combination of Diessel et al and Wada et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the precision

pump taught by Wada et al to move the cell-containing fluid through the channels in the device taught by Diessel et al since Wada et al teach that a precision pump such as a peristaltic pump is a common flow controller used to flow a cell-containing stream to be sorted through a channel network, and allows the cell-containing stream to exit controllably either a waste port or a collection port for efficient sorting.

For all of the above reasons, Applicants' arguments are not found persuasive.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

February 22, 2006

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700